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10/552,460	10/07/2005	Alberto Sardo	P0991US00/BAS	2270
881 STITES & HAI	7590 05/11/201 RBISON PLLC	EXAMINER		
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SUITE 900 ALEXANDRIA	A, VA 22314		ART UNIT	PAPER NUMBER
			1781	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Application No.	Applicant(s)			
Office Action Summary		10/552,460	SARDO, ALBERTO			
		Examiner	Art Unit			
		ELIZABETH GWARTNEY	1781			
	The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1) 又	Responsive to communication(s) filed on 19 Ja	nuary 2010				
· · ·						
3)□	, 					
٥/١	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
	closed in accordance with the practice under Ex pane Quayle, 1935 C.D. 11, 455 C.G. 213.					
Dispositi	on of Claims					
4)🛛)⊠ Claim(s) <u>39-43,47,48,54 and 56-76</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)	5) Claim(s) is/are allowed.					
· · · · · · · · · · · · · · · · · · ·	6)⊠ Claim(s) <u>39-43,47,48,54 and 56-76</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/or	election requirement.				
Applicati	on Papers					
9)□	The specification is objected to by the Examine	r				
-			vaminer			
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority ι	ınder 35 U.S.C. § 119					
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
2) Notic 3) Inform	t(s) e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te			

DETAILED ACTION

1. The Amendment filed January 19, 2010 has been entered. Claims 74-76 have been added. Claims 39-43, 47-48, 54 and 56-76 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim72 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 72 recites "comprising treating said fruit or vegetable by applying such chemical treatment to said fruit or vegetable, and applying a composition comprising lecithins and/or derivatives thereof and a chemical treatment agent to said fruit or vegetable." While there is support in the specification for treating said fruit or vegetable by applying such chemical treatment to said fruit or vegetable and applying a composition comprising lecithins and/or derivatives thereof (originally filled claim 72, page 14, lines 12-25), there is no support for applying a chemical treatment and a composition with both lecithin and a chemical treatment agent.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "comprising treating said fruit or vegetable by applying such chemical treatment to said fruit or vegetable, and applying a composition comprising lecithins and/or derivatives thereof and a chemical treatment agent to said fruit or vegetable" renders the claim indefinite because it is not clear what the difference is between a chemical treatment and a chemical treatment agent or whether the step of applying "such chemical treatment" is distinct from the application of the chemical treatment agent applied as part of a composition with lecithin.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the

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various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 65, 72, 73 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2).

Regarding claim 65, 72, 73 and 76, Garcia-Mina et al. disclose a method for treating fruits and vegetables comprising bathing the fruits and vegetables at a temperature of 45° to 50°C in a composition comprising lecithin and a fundamental active ingredient, eugenol (Abstract, [0019], [0032]). Garcia-Mina et al. also disclose an aqueous solution comprising lecithin (i.e. composition including water-[0035]/Formula 1, [0042]/Formula 2) and diluting the solution prior to bathing fruits and vegetables (*see* in a bath, diluted, concentration: 200-1000 ppm - [0032], claims 4-5). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e. lecithin - [0019]), and 25% water ([0035]). Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13).

While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 ([0019]), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm (given product is treated in a

solution of 1 to 10000 ppm concentration wherein 10-30% of the solution comprises lecithin - claims 3-4).

While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

10. Claims 39-43, 47-48, 54, 56-64, 66-71, 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia-Mina et al. (EP 1 106 070 A2) in view of Schur (US 6,514,551).

Regarding claims 39, 74 and 75, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising applying a composition containing a fundamental active ingredient, eugenol, and a surface active including lecithin (Abstract, [0001], [0016], and [[0019]). Garcia-Mina et al. disclose a composition wherein the surface active is in an aqueous solution (i.e. composition including water-[0035]/Formula 1, [0042]/Formula 2) and diluted (*see* in a bath, diluted, concentration: 200-1000 ppm - [0032], claims 4-5). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e.

lecithin - [0019]), and 25% water ([0035]). Garcia-Mina et al. also disclose that the composition dose is between 1 and 10000 ppm ([0019]/L13).

While it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

Further, Garcia-Mina et al. disclose a composition comprising between 10% and 30% surface active compound (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80). While there is no explicit disclosure regarding the amount of lecithin, given that Garcia-Mina disclose the equivalence and interchangeability of using lecithin with using Twen 80 ([0019]), since Garcia-Mina disclose a composition comprising between 10% and 30% surface active (see preparation of 1 kg. product – [0031], claim 3) that is known under the tradename Twen 80 and or Span 80), it would have been obvious to one of ordinary skill in the art to also use lecithin in amount of between 0.1 and 3300 ppm (given product is treated in a solution of 1 to 10000 ppm concentration wherein 10-30% of the solution comprises lecithin - claims 3-4).

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While Garcia-Mina et al. disclose a composition dissolved in an aqueous base and diluted with water, the reference does not explicitly disclose that the composition is dissolved in 30% to 60% vegetable oil.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have used vegetable oil, as taught by Schur, to dilute the composition of Garcia-Mina et al. because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

As fluidity and ease of application are variables that can be modified, among others, by adjusting the amount of vegetable oil base, the precise amount of vegetable oil base would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of vegetable oil cannot be considered critical. Accordingly, it would have been obvious one of ordinary skill in the art at the time the invention to have adjusting by routine processing the amount of vegetable oil in the composition of modified Garcia-Mina et al. to obtain the desired fluidity and application efficiency.

Regarding claims 40-41, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithins

contain 30% to 60% lysolecithins. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, including between 30% and 60% of all of the lecithin, in the composition of Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

Regarding claim 42, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Since Garcia-Mina et al. disclose lecithin ([0019]), the limitations of this claim have been met.

Regarding claim 43, Garcia-Mina et al. disclose all of the claim limitations as set forth above and that the treatment agents and lecithin are formulated to be administered simultaneously ([0019]).

Regarding claims 47 and 54, Garcia-Mina et al. disclose a composition containing a treatment agent, i.e. eugenol, for fruits and vegetables and lecithin (Abstract, [0019]). Specifically, Garcia-Mina et al. also disclose a composition that comprises 15% eugenol, 20% surface-active complex (i.e. lecithin - [0019]), and 25% water ([0035]).

While Garcia-Mina et al. disclose a composition dissolved in an aqueous base and diluted with water, the reference does not explicitly disclose that the composition is dissolved in 30% to 60% vegetable oil.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have used vegetable oil, as taught by Schur, to dilute the composition of Garcia-Mina et al. because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

As fluidity and ease of application are variables that can be modified, among others, by adjusting the amount of vegetable oil base, the precise amount of vegetable oil base would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of vegetable oil cannot be considered critical. Accordingly, it would have been obvious one of ordinary skill in the art at the time the invention to have adjusting by routine processing the amount of vegetable oil in the composition of modified Garcia-Mina et al. to obtain the desired fluidity and application efficiency.

Regarding claim 48, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agents and lecithin are formulated in order to be administered simultaneously ([0019]).

Regarding claims 56-57, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the ratio of lecithin to the treatment agent is about 1.3 (*see* 20% surface active complex (i.e. lecithin-[0019]) to 15% eugenol – [0035]).

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Regarding claim 58, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the lecithin contains between 5% and 15% lysolecithin. A skilled artisan would know that the hydrolyzed form of lecithin, lysolecithin, has superior emulsification properties to lecithin. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have replaced a portion, or all of the lecithin, in the composition of modified Garcia-Mina et al. with lysolecithin for the purpose of making a more stable emulsion with the treatment agent ingredient.

Regarding claim 59, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose applying the composition to fruits and vegetables (Abstract, [0032]).

Regarding claim 60, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water to a dose between 1 and 10000 ppm ([0019], [0032]).

Regarding claim 61, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is diluted in water and applied at a temperature of from 45° to 50°C ([0032]).

Regarding claims 62-63, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the composition is applied by mean of showering or immersion ([0019]/L11-12). Garcia-Mina et al. also disclose use of the composition post-harvest ([0016/L37).

Regarding claim 64, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. does not disclose that the application of

the composition is carried out before harvesting the fruit or vegetable. Given that the composition is used to control post-harvest pathologies, it would have been obvious to a skilled artisan to have applied the composition to the fruit or vegetable at any time prior to distribution and achieve the same benefits.

Regarding claim 66, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. While Schur teaches mixing lecithin and a microbiologically active substance (i.e. eugenol) in a vegetable oil base, the reference does not explicitly teach adding lecithin to the vegetable oil base followed by addition of the active substance. To switch the order of performing process steps, i.e. the order of the addition of the ingredients into the final composition, would be obvious absent any clear and convincing evidence and/or arguments to the contrary (MPEP 2144.04[R-1]).

"Selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results."

Regarding claim 67, Garcia-Mina et al. disclose a method for controlling post-harvest pathology of fruits and vegetables (i.e. affliction of pathogenic agents and processes of chemical degeneration of the skin) comprising mixing a composition containing an active ingredient selected from eugenol, terpineol, and geraniol and a surface active including lecithin (Abstract, [0001], [0016], [0019]) in an aqueous base (*see* [0035]/Formula 1 and [0042]/Formula 2).

Garcia-Mina does not disclose that the lecithin and treatment agents are mixed in an oil base or that the method is for preserving lecithins and/or derivatives thereof.

Schur teaches a composition for impacting the surface of microbially perishable products comprising a microbiologically active substance and lecithin diluted (i.e. mixed) in vegetable oil (C2/53-54, C6/L3-6, C9/L24-30,46-53).

Garcia-Mina et al. and Schur are combinable because they are concerned with the same field of endeavor, namely, stabilization of microbially perishable products. It would have been obvious to one of ordinary skill in the art at the time of the invention was made to have mixed the treatment agent and lecithin in Garcia-Mina et al, with vegetable oil, as taught by Schur, because doing so would amount to nothing more than the use of a known food grade dilutant for its intended use in a known environment to accomplish entirely expected results.

The recitation that says the method is for preserving lecithins does confer patentability to the claim since statements in the preamble reciting the purpose or intended use of the claimed invention which do not result in a manipulative difference between the claimed invention and the prior art do not limit the claim and do not distinguish over the prior art process. See, e.g., *In re Otto*, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963); *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997) and cases cited therein, as it has been held that the recitation of a new intended use for an old product does not make a claim to that old

product patentable. *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). See also MPEP § 2111.02 and § 2112 - § 2112.02.

Regarding claim 68, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent has fungicidal properties ([0002]/L8).

Regarding claim 69, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent is eugenol (Abstract, [0019]).

Regarding claims 70-71, modified Garcia-Mina et al. disclose all of the claim limitations as set forth above. Garcia-Mina et al. also disclose that the treatment agent represents 40% by weight of the lecithin (*see* preparation of 1 kg. product where eugenol is 40% of the surface active substance – [0031]).

Response to Arguments

11. Applicant's arguments filed January 19, 2010 have been fully considered but they are not persuasive.

Applicants have amended to the claims to provide that the chemical treatment agent of the claims consists essentially of eugenol or salts thereof. Therefore, applicants argue that the presently-claimed method and compositions are distinguished over the Garcia-Mina reference which requires additional active chemical treatment agents beyond eugenol. Applicants note that Garci-Mina requires a "second active ingredient" in addition to a "main active ingredient."

First, while it is recognized that the phrase "consisting essentially of" narrows the scope of the claims to the specified ingredients and those which do not materially affect

the basic and novel characteristics of the claimed invention, absent a clear indication of what the basic and novel characteristics are, "consisting essentially of" is construed as equivalent to "comprising". Further, the burden is on the applicant to show that the additional ingredients in the prior art, would in fact be excluded from the claims and that such ingredients would materially change the characteristics of the applicant's invention, See MPEP 2111.03.

Second, even *if* applicant shows that the additional ingredients in the prior art would in fact be excluded from the claims, claims 39 and 47 are directed to a "composition *comprising*." In this case, the transitional phrase "comprising" is openended and does not excluded additional ingredients. Similarly claims 65, 72-73 and 75-76 are directed to "A method . . . comprising" wherein the transitional phrase "comprising is open-ended and does not exclude additional steps including the application of additional ingredients.

Applicants find that active ingredients, such as those disclosed in Garcia-Mina are phytotoxic to the treated plants. Applicants note that "embodiments of the claimed composition, and related methods, make use of a limited amounts of eugenol as a unique active ingredient, and provide eugenol in a specific corresponding range of amounts relative to lecithin amounts that are used, the combination of which leads to a far improved inhibition of phytotoxicity."

In this case, eugenol is also known to be phytotoxic to fruit and vegetables (Specification, page 2, lines 10-19). It is unclear how "other" active ingredients would contribute differently to phytotoxicity than eugenol. Clarification is requested.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH GWARTNEY whose telephone number is (571)270-3874. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./ Examiner, Art Unit 1781

/Keith D. Hendricks/ Supervisory Patent Examiner, Art Unit 1781